

### **REMARKS**

Claims 1-36 are pending. Claims 1-36 stand presently rejected. On an initial note, Applicants wish to thank the Examiner for indicating the informalities with respect to Claim 25. The claim has been amended, accordingly. Applicants have also amended Claims 2-4, 8, 10-11, 16-17, and 33-35, without prejudice. Support for the amendment to Claim 2 can be found, for example, in Application FIG. 13. Support for the amendment to Claim 3 can be found, for example, in Application para. [0050]. Support for the amendment to Claim 4 can be found, for example, in Application para. [0049]. Support for the amendments to Claims 8 and 11 can be found, for example, in each respective claim, itself. Support for the amendment to Claim 10 can be found, for example, in Application para. [0076]. Support for the amendment to Claim 16 can be found, for example, in Application para. [0050] and in the claim, itself. Support for the amendment to Claim 17 can be found, for example, in Application para. [0078]. Support for the amendment to Claim 33 can be found, for example, in Application paras. [0052]-[0053]. Support for the amendment to Claim 34 can be found, for example, in Application paras. [0050] and [0053]. Support for the amendment to Claim 35 can be found, for example, in Application para. [0053].

The Applicants submit that these minor amendments and corrections herein are made without prejudice as to patentability, including the doctrine of equivalents, and no new matter has been added. Although Applicants do not believe any fees are required, the Commissioner is authorized to charge any fees or provide any refunds to the deposit account of Bracewell & Giuliani LLP, 50-0259 (Attorney Docket No. 0771CG.035249).

### **Claims 1-36 are Non-Obvious**

Claims 1-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chudy et al., U.S. Patent Publication No. 2004/0088187 (hereinafter "Chudy") in view of a Department of Health report entitled "A Pharmacy Service for Prisoners" (hereinafter "DOH"). Applicants respectfully traverse the rejection.

### **The Present Application**

Various embodiments of the present invention feature computerized systems, program storage media/program product, and methods which monitor/manage the inventory of pharmaceuticals and the dispensation of prescribed medication in conjunction with computerized records, for inmates. Various embodiments of the invention make comprehensive electronic medical records visible to the pharmacist to allow the pharmacist to make decisions regarding the suitability of physician prescribed medications, beyond mere drug interactions. Further, various embodiments of the invention include provisions for documenting actual dispensation, receipt, and verified consumption of a prescribed medication. Such features, and others, are provided to enhance/optimize the pharmacy management system for inmates from the origination of a medication order to the actual delivery and consumption of the medication.

### **The Cited Documents**

#### **The Chudy Patent**

Chudy, for example, describes a system and methods for managing pharmacy workflow associated with fulfillment of prescription orders for medications and health-related products in a pharmacy environment. Particularly, the system is described as sequencing prescriptions to minimize costs associated with filling of prescription orders, to minimize human involvement in the prescription order fulfillment process, to reduce the amount of time required to fulfill a prescription order, to reduce the spatial [(walking)] distance required to be traveled by pharmacy technicians to fulfill prescription orders, and to reduce the potential for errors in the fulfillment process.

Chudy, however, as a minimum, does not disclose, teach, or suggest a system or method which includes verifying suitability of a medication based on a medical record review in a combined automated and/or manual process directed to a relatively comprehensive electronic medical record, or forming a record in a computer indicating a verification of whether a patient actually took the prescribed medication. There are also other differences discussed below.

### The DOH Report

The DOH report by England's Department of Health sets out findings and recommendations supporting a desire/goal to integrate prison pharmacy services into England's national health services, along with an identification that 5-year funding has been allocated to fund future projects to realize the desire/goal. The DOH article, however, does not disclose the actual structure of functional systems, program product, or process steps. In fact, most, if not all of the recommendations provided in the report identify a shortfall in prison pharmacy services, without detailing the "hardware" to fix the shortfall.

### No Prima Facie Case of Obviousness

To establish a *prima facie* case of obviousness, there are seven primary rationales, which the Examiner can use to support a rejection under 35 U.S.C. § 103: "(A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of a known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) 'Obvious to try'--choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; [and] (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention." See MPEP 2143.

Applicants respectfully submit that there would be no motivation to combine references under either rationale (A)-(F) at least because: the cited documents together do not include each element claimed, as required by rationale (A); Chudy (the primary reference) does not disclose components that could be readily substituted with those of the DOH article to build Applicants'

claimed embodiments, as required by rationale (B); Chudy does not disclose sufficient components to be considered a base device or comparable device such that the claimed embodiments of Applicants' invention could be seen as an "improvement," as required by rationale (C), and even if so, no known technique to improve similar devices has been premised; Chudy does not disclose sufficient components to be considered a base device, nor does Chudy or the DOH article contain known techniques applicable to such device, as required by rationale (D); there is no finding that there exists a finite number of identified, predictable potential solutions to a recognized need or problem, as required by rationale (E); and there is no finding that the scope and content of the cited documents include a similar or analogous device, as required by rationale (F). *See* MPEP 2143. Of course, other missing factors also exist.

Further, as described in more detail below, there is no teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; or a finding that there was reasonable expectation of success, as required by rationale (G). Nor do the cited references or reference teachings, when combined, teach all the claim elements. A more detailed discussion follows.

#### No Recognition of the Problem or the Source of the Problem

Nothing in either of the cited patent documents, to the extent these might be prior art, recognizes the problems or solution identified by the Applicants and as set forth in the claimed embodiments of the invention. For example, nothing in either of the cited documents, alone or in combination, recognizes a need to monitor the dispensation of prescribed medications to inmates in correctional facilities in conjunction with computerized records, a human pharmacist reviewing comprehensive medical records to verify suitability of a prescription order beyond that to merely ensure that there does not exist any adverse drug interactions (e.g., claimed embodiments inject additional human involvement in an otherwise automated process).

No Motivation to Combine Reference Teachings

First and foremost, Chudy at least implicitly, if not explicitly, *teaches away* from the direction in which the inventor went. As noted above, Chudy describes as one of its primary objectives, a pharmacy automation system and method of pharmacy workflow management which would minimize human involvement in the prescription order fulfillment process. See Chudy, para. [0015]. This is in stark contrast to the Applicants' disclosure which teaches significant human involvement in the prescription order release process and in the documentation of medication dispensing, receipt, and consumption verification. Further, Chudy describes as one of its primary objectives, a pharmacy automation system and method of pharmacy workflow management which reduces the spatial distance required to be traveled to fulfill a prescription order. See Chudy, para. [0017]. This objective clearly shows that Chudy was designed for a self-contained single-environment system. In contrast, Applicants system is designed to extend over substantial geographic expanses to service multiple correctional facilities. This was simply not a concern for Chudy.

Additionally, even if, for the sake of thoroughness, one were to discount that Chudy teaches away from the claimed embodiments of Applicants' invention, the nature of the problems to be solved, in general, and specifically as disclosed by the cited documents or any need or problem known in Applicants' field of endeavor at the time of the invention *and* addressed by the Application, provide no such motivation, as required by MPEP 2141.01(a)I (citing KSR International Co. v. Teleflex Inc., 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1397 (2007)) (emphasis added). Chudy perceived a need for an automated pharmacy system and method for managing "pharmacy workflow [(e.g., personnel spatial movement)]...associated with fulfillment of prescription orders for medications and health-related products in a personnel-driven pharmacy operation." See Chudy, para. [0023], lines 1-5. Applicants addressed no such need or industry problem in their Application, as required by MPEP 2141.01(a)I, but rather, leveraged resources of geographically remote facilities to ensure on-time processing and dispensation of suitable prescribed medication.

Further, as noted above, the DOH article does not provide such required motivation. Notably, the DOH article provides observations and recommendations, but without the "how."

Accordingly, one skilled in the art would also not be motivated to combine teachings of the cited documents in order to try to build the Applicants' invention. Correspondingly, Applicants respectfully submit that for these reasons alone, Independent Claims 1, 16, 25, 27, 33, 34, and 35, along with their respective dependent claims, have been shown to be allowable and define over the cited documents.

#### No Reasonable Expectation of Success

As Chudy deals with a self-contained, single facility pharmacy dispensing unit personnel workflow management and methods, modifying Chudy to perform in a prison clinic, without a teaching of the components external to the correctional facility or methods needed to build the complete system disclosed by Applicants would result in a requirement for undue experimentation. Further, although Chudy indicates that customer medical records may be searched to determine potential adverse drug interactions (Chudy, para. [0121]), Applicants understand this reference terminology directed to "medical records" to mean other prescription orders, or records thereof, and not "electronic medical records" which would be understood by one skilled in the art reading Applicants' specification to be comprehensive medical records in electronic form including combinations of patient conditions such as, for example, demographic information, vital signs, lab work results, x-rays, medical checkup data, allergies, physical exam results, family history, list of current medications, drug formulary, and the like, applied therapies (data to detect duplicate therapies) along with by-medication dosing history, information related to each inmate, such as a list of pending regular and refill prescriptions for the inmate, a list of medications currently on hold for the inmate, the medication profile for the inmate, the medication history for the inmate, inmate demographic and allergy information, a list of problems associated with each inmate, lab results, records related to compliance or medication administration record with prior prescriptions, clinical review data for a prescription, etc. See Application, paras. [0050] and [0067] and FIGS. 13-14.

With respect to both Chudy and DOH, Applicant respectfully submits that taking a civilian system and dropping it into a correctional facility system having substantially different requirements and regulations, without a teaching of modifications needed to satisfy the different requirements and regulation, would further result in a requirement for undue experimentation.

Accordingly, Applicants respectfully submit that as it would require undue experimentation to try to build the claimed embodiments of Applicants' invention using the teachings of Chudy and DOH, if attempts were made to do so without using the subject Application specification as a roadmap, Independent Claims 1, 16, 25, 27, 33, 34, and 35, along with their respective dependent claims, have been shown to be allowable and define over the cited documents.

The References Do Not Teach All Claim Elements

Applicants respectfully submit that even if one were to ignore, for the sake of thoroughness, the lack of motivation to combine references, the lack of a reasonable expectation of success, or that Chudy teaches away from the direction to which the Applicants went, Applicants further respectfully submit that neither of the cited documents, alone or in combination, teach all claim elements. Note, Claims 1-36 were rejected as being obvious under 35 U.S.C. § 103(a) as being unpatentable over Chudy in DOH, with Claims 1, 16, 25, 27, 33, 34, and 35, being independent claims.

Regarding Independent Claim 1, as a minimum, neither Chudy nor DOH, alone or in combination, disclose, teach, or suggest either a method which includes reviewing an electronic medical record including a patient's medical history (beyond a mere prescription record), authorizing release of a prescribed medication verified and suitable (e.g., based on a medical record review of the electronic medical record), or forming a record in a computer indicating a verification of whether a patient actually took the prescribed medication. Note, one skilled in the art would understand that the claim is directed to outpatient medication delivery in correctional facilities and not delivery in a hospital environment or other closed medical system, which falls under a different set of rules and regulations

First, the Office Action identifies that official notice was taken with respect to access to a patient's medical history, premising that "the pharmacist must determine what prescription has been approved for fulfillment [of the prescription order] which requires a patient's medical history..." Applicants respectfully submit that only the "prescription order" is necessary, and thus, providing the pharmacist access to a patient's medical history would not be inherent.

Chudy paras. [0077]-[0079] and [0082] were further cited as allegedly teaching a pharmacist reviewing an electronic medical record to verify that the prescribed medication is suitable for the patient, and paras. [0123]-[0124] were cited as allegedly teaching authorizing release and verifying suitability of a pharmaceutical. Notably, the citations in general, and para. [0082] in particular, identify that it is the proper filling of the "prescription order" that is being verified--with verification being defined as determining that the *correct* medication is in each associated container--i.e., the pharmaceutical identified the prescription order is the same pharmaceutical loaded into the respective container. Accordingly, such "second set of eyes review" at the dispensing level to prevent the error made famous in the movie "It's a Wonderful Life" is not a teaching of verifying *suitability* of the medication, i.e., whether the prescription order identifies a medication that would not be safe or appropriate for the specific patient, e.g.; whether it would result in allergen reactions or whether it would duplicate therapies, etc.

Chudy para. [0145] was also cited as teaching delivering a unit packet of prescribed medication to a "[correctional] facility unit" that houses the patient. Notably, the fulfillment centers 73, 75, 70 (FIG. 5) identified therein are not facilities that house a patient.

Chudy Fig. 28 was further cited as teaching verifying that a patient took the unit packet of prescribed medication. Applicants respectfully submit, however, that FIG. 28 features a screen showing filled prescriptions in a state prior to the pharmacist verifying the correct pharmaceutical was loaded in the correct container. See Chudy, para. [0164]. Even if one were to consider this to be a teaching of forming a record of dispensing a medication, it would not be considered by one skilled in the art to be a teaching of forming a record of verification that an inmate *took* (consumed) the prescribed medication. Further, as described previously, Chudy,



instead, teaches away from that level of human involvement in the prescription order fulfillment process. See Chudy, para. [0015].

Applicants further respectfully submit that even if there were a motivation to combine the teachings of the DOH report with that of Chudy, applying Chudy to a correctional facility clinic would not fill in the missing elements described immediately above. Accordingly, Applicants respectfully submit that as neither of the cited documents, alone, nor in combination, disclose, teach, or suggest each and every element of Claim 1, for this reason alone, Claim 1 defines over the cited documents.

For similar reasons, the other independent claims also define over the cited documents. Independent Claim 16, for example, is nonobvious over the cited documents, as Claim 16, as a minimum, similarly features the step of reviewing an electronic medical record beyond that of a year prescription order or history record, and the step of verifying suitability of the prescribed medication responsive to the review of the electronic medical record, shown to be not disclosed, taught, or suggested by the cited documents.

Independent Claims 25 and 27, for example, are also nonobvious over the cited documents, as Claims 25 and 27, as a minimum, feature the three-step process of forming a record in the computer of dispensing a unit packet of the prescribed medication to the inmate; forming a record in the computer indicating verification that the inmate received the unit packet of the prescribed medication; and forming a record in the computer verifying whether the inmate took the unit packet of the prescribed medication, not disclosed, taught, or suggested by the cited documents. Beneficially such can provide evidence that is easily imported into verification reports, thus, providing the correctional facility evidence that the correctional facility at least attempted to properly provide medical services to a specific inmate to rebuff any inmate grievances to the contrary.

Independent Claims 33 and 35 are also nonobvious over the cited documents, as Claims 33 and 35, as a minimum, feature, at least in part, a medication dispensation workstation positioned at the correctional facility and configured to enable the prescribed medication to be

dispensed to an inmate *and* to enable a medication compliance history to be recorded in the computer memory, not disclosed, taught, or suggested by the cited documents.

Independent Claim 34, for example, is also nonobvious over the cited documents, as Claim 34, as a minimum, features, at least in part, a pharmacist review workstation configured to enable a pharmacist to *simultaneously* review the inmate's medical information (including laboratory work results and medical check-up data) and an inmate's prescription, not disclosed, taught, or suggested by the cited documents.

Accordingly, Applicants respectfully submit that as neither of the cited documents, alone, nor in combination, disclose, teach, or suggest each and every element of either of the independent claims, Independent Claims 1, 16, 25, 27, 33, 34, and 35, and the respective dependent claims (Claims 2-15, 17-24, 26, 28-32, and 36) have been shown to be allowable and define over the cited documents.

Dependent Claims 2-15, 17-24, 26, 28-32, and 36, also are independently novel and nonobvious. Claim 2, for example, features, at least in part, automatically reviewing the electronic medical record for drug-drug interactions[, duplicate therapies,] and allergies. Chudy, para. [0149] cited in the Office Action as providing such teaching, in contrast, describes a sequence sheet (bag) which provides detailed instructions for a patient taking the medication. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 3, for example, features, at least in part, manually reviewing [laboratory results contained within] the electronic medical record prior to authorizing release of the prescribed medication. Chudy, para. [0082], cited in the Office Action as providing such teaching, in contrast, describes the pharmacist reviewing the prescription order at the filling/check workstation to ensure that the correct medication was placed in the correct container. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 4, for example, features, at least in part, comparing the prescribed medication with a drug formulary of approved medication stored in the computer memory upon entry of a

prescription into the computer. Chudy, paras. [0120]-[0121], cited in the Office Action as providing such teaching, in contrast, makes no mention of a drug formulary. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 5, for example, features, at least in part, recommending a substitute medication if the step of comparing the prescribed medication with the drug formulary of approved medication indicates the prescribed medication is not contained with the drug formulary of approved medication. Chudy, paras. [0117] and [0120]-[0121], cited in the Office Action as providing such teaching, in contrast, describe receiving and entering a prescription order in the Chudy system. No mention is made of a drug formulary or a pharmacist recommending a substitute. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 6, for example, features, at least in part, verifying that the inmate is the inmate who has been prescribed the prescribed medication prior to forming a record in the computer of dispensing.... Chudy, Fig. 28, cited in the Office Action as providing such teaching, in contrast, illustrates a computer screen showing prescription orders in a state where prior verification has not been undertaken. See Chudy, para. [0164]. Note, verification according to Chudy is defined as ensuring that the correct medication is in the correct container (see para. [0082]), and not the identity of an inmate, or as a prerequisite to creating a dispensing record. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 7, for example, features, at least in part, adding inmate enrollment data records to the electronic medical record if information related to a new inmate is not already present. Chudy, para. [0078], cited in the Office Action as providing such teaching, in contrast, describes entering prescription order information into a pharmacy computer. As discussed previously, a prescription order would not be considered by one skilled in the art to be a medical record or an electronic medical record. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 8, for example, features, at least in part, sorting each unit packet into a shipment in accordance with a shipping schedule for delivery of the unit packets to each correctional facility after the prescribed medication has been labeled. Chudy, Fig. 7E and para. [0090], cited in the Office Action as providing such teaching, in contrast, describe dispensing by an automated dispensing machine shown in Fig. 5. No mention is made of sorting medication into a shipment in accordance with a shipping schedule. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 9, for example, features, at least in part, updating the inventory of pharmaceuticals at the correctional facility. Chudy, paras. [0028]-[0029] and [0124]-[0132], cited in the Office Action as providing such teaching, in contrast, describe updating internal pharmacy inventory. Notably, Chudy makes no mention of tracking inventory for an institutional customer. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 10, for example, features, at least in part, caching each electronic medical record for each inmate contained within each shipment scheduled to be shipped within a predefined time period. Applicants respectfully submit that it would not be inherent to cache externally maintained electronic medical records on a local pharmacy computer--features of the Applicants claimed embodiment and provided as a fault tolerance feature to prevent an interruption in processing, and thus, an unacceptably late medication delivery in the event of a network failure. This type of caching is in contrast to normal computer memory caching. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 11, for example, features, at least in part, caching data related to each label to be printed for each shipment scheduled to be shipped within a predefined time period prior to printing the label. Chudy, para. [0030], cited in the Office Action as providing such teaching, in contrast, makes no mention of dealing with multiple shipments or delayed processing, but rather appears to describe printing in filling sequence. The caching is a feature provided by Applicants to prevent processing delays caused by network failure--a problem also not addressed by Chudy.

Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 12, for example, features, at least in part, forming a verification record indicating that the inmate did not take the medication, subsequently locating the unit packet, and returning the unit packet of prescribed medication if suitable for future use, to a central pharmacy for reclamation, and adjusting the inventory of pharmaceuticals. As noted above, Chudy does not disclose, teach, or suggest creating a record indicating whether or not a customer actually consumed a dispensed medication. Further, Chudy, paras. [0033] and [0090], cited in the Office Action as providing a teaching of the locating step, and paras. [0117]-[0118] and [0153] cited as teaching the returning and adjusting inventory steps, in contrast, describe dispensing medication (the opposite of returning). Nothing is mentioned of locating and returning medication to a central pharmacy or adjusting the inventory in response to such returns. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 13, for example, features, at least in part, adjusting the inventory of pharmaceuticals for inmates in correctional facilities. Chudy, para. [0125], cited in the Office Action as providing such teaching, in contrast, describes tracking internal pharmacy inventory including dispensing machine inventory, but not the remote inventory of any institutional customers. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 14, for example, features, at least in part, adjusting the inventory of pharmaceuticals for inmates in correctional facilities. Chudy, para. [0153] and official notice, cited in the Office Action as providing such teaching, in contrast, makes no mention of a capability of Chudy to bypass any of its process steps for subsequent refills. Applicants respectfully submit that Chudy is a workflow management system which requires adherence to its stated process steps. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

Claim 15, for example, features, at least in part, scheduling a time period in which the prescribed medication is to be dispensed to the inmate. Chudy, para. [0149], cited in the Office Action as providing such teaching, in contrast, describes providing a recommended time of day that the medication should be *taken*, which would not be understood to be the same time that the medication is being *dispensed*. Accordingly, such would not provide one skilled in the art, a disclosure, teaching, or suggestion of the claimed features.

### Summary

Applicants respectfully submit that a prima facie case of obviousness has not been established. The primary reference, at least inherently, teaches away from the direction to which the Applicants went. There is no motivation to combine reference teachings; due to missing elements there would be no expectation of success in combining the teachings in order to build the claimed embodiments of the Applicants invention; and the cited references, alone or in combination, do not teach each and every claim element. Further, even if it were determined that a prima facie case of either anticipation or obviousness was established, Applicants submit that Applicants have submitted sufficient evidence to rebut such a showing.

In commenting upon the references and in order to facilitate a better understanding of the differences that are expressed in the claims, certain details of distinction between the references and the present invention have been mentioned, even though such differences do not appear in all of the claims. It is not intended by mentioning any such unclaimed distinctions or making any amendments herein to create any implied limitations in the claims. Not all of the distinctions between the cited patent documents and claimed embodiments of Applicants' present invention have been made by Applicants. For the foregoing reasons, Applicants reserve the right to submit additional evidence showing the distinctions between the claimed embodiments of Applicants' invention to be novel and nonobvious in view of the cited patent documents.

The foregoing remarks are intended to assist the Examiner in re-examining the application and in the course of explanation may employ shortened or more specific or variant descriptions of some of the claim language. Such descriptions are not intended to limit the scope

of the claims; the actual claim language should be considered in each case. Furthermore, the remarks are not to be considered to be exhaustive of the facets of the invention that render it patentable, being only examples of certain advantageous features and differences.

### **CONCLUSION**

In view of the above remarks, Applicants submit that the Application is in condition for allowance. As such, the issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,

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